Research with Human Subjects: The Effects of Commercialization of University-Sponsored Research

IHELG Monograph

89-4

Helen Leskovac
Yale University Law School
New Haven, CT

$5.00
University of Houston Law Center/Institute for Higher Education Law and Governance (IHELG)

The University of Houston Institute for Higher Education Law and Governance (IHELG) provides a unique service to colleges and universities worldwide. It has as its primary aim providing information and publications to colleges and universities related to the field of higher education law, and also has a broader mission to be a focal point for discussion and thoughtful analysis of higher education legal issues. IHELG provides information, research, and analysis for those involved in managing the higher education enterprise internationally through publications, conferences, and the maintenance of a database of individuals and institutions. IHELG is especially concerned with creating dialogue and cooperation among academic institutions in the United States, and also has interests in higher education in industrialized nations and those in the developing countries of the Third World.

The UHLC/IHELG works in a series of concentric circles. At the core of the enterprise is the analytic study of postsecondary institutions—with special emphasis on the legal issues that affect colleges and universities. The next ring of the circle is made up of affiliated scholars whose research is in law and higher education as a field of study. Many scholars from all over the world have either spent time in residence, or have participated in Institute activities. Finally, many others from governmental agencies and legislative staff concerned with higher education participate in the activities of the Center. All IHELG monographs are available to a wide audience, at low cost.

Programs and Resources

IHELG has as its purpose the stimulation of an international consciousness among higher education institutions concerning issues of higher education law and the provision of documentation and analysis relating to higher education development. The following activities form the core of the Institute’s activities:

Higher Education Law Library

Houston Roundtable on Higher Education Law

Houston Roundtable on Higher Education Finance

Publication series

Study opportunities

Conferences

Bibliographical and document service

Networking and commentary

Research projects funded internally or externally
INTRODUCTION

The commercialization of university-sponsored research in the biological sciences in the past decade has had far-reaching effects on the conduct of research, not least on the relationship of researchers and human subjects. Most biological research that has application to human health and welfare must at some point be conducted with human subjects, most of whom volunteer their services and time, or in some cases their bodily tissues and products. Generally, human research subjects receive no financial compensation for their contributions,¹ and courts have not recognized anything more than a quasi-property interest in the human body itself.² In the past decade, however, human subjects
of scientific research have begun to claim various proprietary
interests in their bodies, bodily products, and in the commercial
applications of the research conducted on them, or using their
bodily tissues and products. Not too long ago scientific
researchers and human subjects worked together in a joint research
endeavor, believing they were advancing knowledge and benefiting
humanity. Neither received much compensation, although
researchers of course furthered their personal careers by their
work and human subjects had the satisfaction that often accompanies
altruistic behavior. Now in the interest of technology transfer,
universities and researchers engage in mutually profitable
contractual arrangements with businesses that can develop
commercially valuable products from the research. I argue that commercialization in this context presents a challenge use to reconceive or reconstitute social roles and relationships in research with human subjects. Thus the transformation and the increasing commercialization of university-based research require a re-evaluation of the philosophy and conduct of research with human subjects.

Part I reviews the commercialization of university-sponsored research as a result of increasing cooperation of university and industry, particularly in the biological sciences. Part II examines the effect of commercialization on research with human subjects, focusing on the issue of the subject's rights of
autonomy and property in relation to the research. Property

interests in the human body itself and its tissues or bodily

products are explored in Part III. I conclude that

commercialization of research has changed the relationships of

researchers and human subjects and thus requires changes in the

regulation of research with human subjects and in the law

protecting proprietary interests in the human body.
I. UNIVERSITY AND INDUSTRY RESEARCH LINKS

About ten years ago universities began in earnest to welcome and solicit multi-million dollar contractual agreements with industrial sponsors for the purpose of pursuing research leading to efficient technology transfer, and mutual profit. Critics within and without the university voiced concerns that these collaborations were incompatible with the university's traditional missions of education, research, and service. Today, these voices are seldom heard, and for some the doubts have been put to rest. Nevertheless, it is apparent that there are demonstrable changes in the behavior of universities and university-based
researchers, particularly in the biological sciences, as a result

of increased university-industry ventures.

A. Cooperation of universities and industry

The increased cooperation of universities and industry as research partners is partly a result of spectacular advances in biology and chemistry basic research occurring at the same time as the federal government cut-back or declined to increase support of scientific research. Basic and applied research in these fields have so converged that discoveries transfer very quickly into potentially profitable techniques and products. This boom in
biotechnology, providing employment, profits, and new health
products, also offers promise of a generous source of support for
university-sponsored research.

Today nearly every research university has entered into
contractual agreements with industrial sponsors for the purpose of
pursuing mutually profitable cooperative research and technology
transfer. Such agreements are not a new phenomenon. Research
universities and industry have a long history of cooperation in
developing and supporting research projects. Generally, the
linkages wax and wane depending on the level of government
support of university-based scientific research. Support of
biotechnology alone is much higher, however, as much as 24% of all
biotechnology research at universities.⁹

Both local and federal government have encouraged
university-industry links as a means to facilitate rapid transfer
of knowledge to industry, to alleviate state and national problems
of unemployment, low productivity, and to bolster weakening
international market competition and national defense.¹⁰ In 1981,
the federal government amended patent law to allow nonprofit
institutions such as universities a right of first refusal to
title in inventions¹¹ resulting from the federally funded research
of university researchers.¹² Universities can now seek patents and
license these inventions and collect royalties. They may also
take advantage of federal tax law exemptions for educational
functions and scientific purpose authorized by the Economic
Recovery Tax Act of 1981, as well as the funding provisions for
Research and Development Limited Partnerships of the Internal
Revenue Code. State governments similarly have passed
legislation to foster university-industry research centers and
industrial parks likely to provide employment opportunities,
including tax relief, reduction of workers' compensation and
unemployment insurance, and financial assistance programs for new
and existing industries.
Without new sources of income, university research facilities may be unable to replace aged and outmoded equipment, attract high quality researchers from schools in the US and abroad, or engage in very many significant, and costly, experimental projects. Commercially-driven research may have undesirable side-effects, however, including the potential for a proliferation of narrowly focused, goal-oriented studies\(^{16}\) and increasing secrecy among researchers\(^{17}\) which may slow the advance of knowledge. Critics fear that concentration on short-term goals will divert researchers from the kind of spontaneous, goal-less generation of ideas that in the past provided the basic knowledge
on which much current technology is founded. And certainly, massive infusions of money in support of short-term goals will not necessarily produce useful results either.\textsuperscript{18}

Most universities thus devote considerable time and effort to finding mechanisms to safeguard academic research decisions from the perceived perils of commercialization.\textsuperscript{19} Generally research partnerships explicitly provide for the academic freedom of researchers and publication of the results of the research. Most universities, for example, have patent policies which insure publication of results of research,\textsuperscript{20} although publication may be delayed to accommodate private sponsors.\textsuperscript{21} And many sponsors do
prefer protection of confidential and proprietary information, in order to preserve a monopolistic advantage in the marketplace both as to the original discovery and to those that may follow from it. This commercial incentive is not entirely foreign to the norms and incentives of research which place a high premium on priority of discovery. Hence researchers themselves sometimes have an interest in delaying publication.

B. Commercial activities of university researchers in the biological sciences

In the past, most researchers in the biological sciences received little financial compensation for their research efforts
beyond salaries and research grants. Today, however, to
compensate for the decrease in government spending, researchers in
the biological sciences accept, and many solicit, support in a
variety of forms from industry. Some merely seek research
grants from industrial sources, but many researchers also take on
management positions in private ventures, or found their own
ventures. Others acquire large holdings of stock in companies
that will market products resulting from their research. As a
result, many researchers now frequently behave like entrepreneurs
and businessmen, not only with regard to their search for funding,
peers and students, their attitudes toward the source materials they use, and their proprietary interests in the work they produce. 27

Clearly the conduct of research in the biological sciences has changed dramatically in the past ten years. 28 Of necessity researchers and university now must evaluate research for possible patenting and commercial application. Given the decline in federal funding, it is prudent to seek to capture some of the value and profit potential of research. For researchers, this is especially important because their salaries are paid not from university funds, but rather from the research grants they have
been awarded. This makes even more tenuous the allegiance researchers, like other academics, have to particular universities because of the peripatetic nature of the academic career. Hence they are likely to be very interested in engaging in the commercialization of their own work.

Once rare, the researcher-entrepreneur has become so commonplace that just a few years ago, the New England Journal of Medicine adopted a policy of requiring contributors to disclose their financial interests in the research they reported. Many universities also require researchers to report outside involvements, with varying degrees of formality and specificity.
In California, state conflict of interest rules require researchers who receive support from private entities to disclose their financial interests in those entities to the university and a state agency, and federal granting agencies require disclosure of outside interests too. There is no requirement, however, that researchers disclose financial interests in their research to human subjects on whom the researchers are experimenting.

The researcher in effect has become a trader, a bargainer, *homo economicus*, who seeks work environments conducive to his research and dealmaking, and occasionally he is trading in human bodily products. For this, the researcher may receive a lot of
money, and perhaps rightly so, but none of it goes to the human

subject on whom the research depends. The researcher constituted

as trader casts an entirely different light on the researcher-

subject relationship, however, as well as the researcher's

relationship to the university. Therefore it is necessary to

reevaluate the roles, duties, and responsibilities of researchers

who work with human subjects. The following section will review

the conduct of research with human subjects and focus on some of

the effects of commercialization of university-based research on

the relationship of researchers and human subjects.
II. RESEARCH WITH HUMAN SUBJECTS

Research in areas of knowledge relevant to human physiology and health necessarily is dependent on the contributions of human beings as experimental subjects. Hence, research with human subjects is carried out at nearly every major research university, and is regulated by state and federal law. Guidelines for conducting research with human subjects have been promulgated by the Department of Health and Human Services and the Food and Drug Administration, and are codified in the Code of Federal Regulations (CFR). The codes require institutional review of research with human subjects to assure that human subjects are
exposed only to reasonable risks of injury and that they give informed consent.

A. Institutional Review of Research with Human Subjects

University-based institutional review boards (IRBs), sometimes called human subjects protection committees (HSPCs), review proposed research projects with human subjects carried out by university researchers. The IRBs are composed of scientists, other university-based scholars, and laypersons\(^\text{37}\) who meet regularly to review proposed and ongoing research projects. My research has not revealed any requirement that the IRB scrutinize
research projects for possible negative effects of commercialization. On the contrary, IRBs routinely approve proposals from researchers for projects sponsored by pharmaceutical companies, for example. All IRBs make some review of the value and validity of the projects, however, and carefully scrutinize the consent procedures and consent forms to be signed by human subjects.

Federal regulations require that the human subject be informed of the purposes of the research, procedures to be used, and the experimental nature of the research. The subject must be made aware of the risks and discomforts of participating, the
benefits he or she, or others, may receive from the research, and alternative treatments. In addition, he or she must be informed of the extent of protection of confidentiality of records, compensation or treatment for injuries that may be available, his or her right to terminate participation without penalty, and whom to contact for more information or help in the event of injury.\textsuperscript{41} The federal regulations do not require disclosure of the researcher's personal interests, financial or otherwise, in the research.\textsuperscript{42}

Most IRBs concentrate almost exclusively on review of research proposals. Few monitor the research or the consent
procedure, despite authority to do so provided in the CFR,\textsuperscript{43} most likely because of the potentially high cost in terms of time and expense. Nevertheless, a number of commentators have recommended monitoring,\textsuperscript{44} "at least when there is some probability that the consent process will break down because the subject population is especially vulnerable\textsuperscript{45} or the researcher may be prone to slight the process as a result of negligence\textsuperscript{45} or self-interest.\textsuperscript{47}"

Self-interest comes in many forms, of course. Some commentators and courts assert an inherent conflict of interest between the subject and the researcher's interest in finding new knowledge,\textsuperscript{48} although conflict of value\textsuperscript{49} may be a more accurate
description since conflict of interest implies pecuniary interests. A researcher's stake in his or her research is significant beyond the matter of values or intrinsic interest in the subject matter, however. The research will ultimately contribute to the researcher's stature in the field of study and status rewards such as tenure, promotion, merit pay increases, etc. And today as a result of university-industry links researchers may indeed have additional financial interests in their research.
B. The Relationship of Researchers and Human Subjects

The medical profession in both its clinical and research aspects is clearly concerned about commercial exploitation of patients. For example, the American Medical Association adopted guidelines in 1984 that require physicians, as an ethical obligation of disclosure when they refer patients to medical facilities in which they have a financial interest.\textsuperscript{52} Also with respect to possible conflicts of interest, the New England Journal of Medicine developed a policy that contributors must disclose their interests in the research they report. And several medical researchers and scholars would require human subjects to sign a
consent form that explicitly waives their interests in the
commercialization of research.\textsuperscript{53}

In the biological sciences, researchers are frequently
physicians, and thus their human subjects are also their patients.

Doctors have traditionally had fiduciary relationships with their
patients, and some commentators fear that the introduction of
commercialism threatens the integrity of the doctor-patient
relationship.\textsuperscript{54} Generally, physicians' fiduciary duties to
patients that requires them to act in the best interest of the
patient and with the patient's informed consent.\textsuperscript{55} It is not
clear, however, that physician-researchers have any broader
fiduciary role that would include informing subjects of the commercial value of their participation in the research, and even assisting subjects to receive some compensation resulting from the commercialization. Such a duty may be implicit, however, as a matter of professional ethics and as a result of a broadened scope of informed consent that takes account of a patient's life plans.

of the National Commission. The Belmont Report articulated two
main principles, patient autonomy and protection from unreasonable
risk of injury. In Making Health Care Decisions, the President's
Commission defined autonomy to include the patient's
decisionmaking in the context of his or her own values,
preferences and life plan. In effect, the Commission adopted a
theory of personhood that defines person as character and life
planner. To implement the new informed consent, the Commission
recommended that researchers take pains to give patients and
subjects enough information to make decisions in accord with their
own values and preferences.
If, therefore, as scholars and ethicists have asserted,\textsuperscript{58} patients and human subjects would have different preferences regarding disposition of their bodily tissues and products depending on whether or not the material might generate commercial products and profit,\textsuperscript{59} then researchers must give them information in that regard in order to obtain fully informed consent.\textsuperscript{61} Such a requirement would be fairly simple to implement because procedures for obtaining informed consent are already in place.\textsuperscript{62} The federal regulations should be amended to include this requirement,\textsuperscript{63} in light of the potential changes in the relationship of human subjects, researchers and universities.
C. The Proprietary Claims of Human Subjects

Research subjects occasionally learn of the commercialization of research in which they participated as human subjects. These research subjects are to be distinguished from subjects who from the beginning know that the research is conducted or funded by a commercial entity for the purpose of eventually preparing new commercial products, and presumably voluntarily and knowingly consent, and many of whom are paid for their services as subjects. There is little literature on human subjects who have demanded more than payment for their time and services. My research reveals two significant examples, only one
of which went to trial.

1. The Hagiwara cell line

In 1982, a Japanese post-doctoral student at the University of California, San Diego, (UCSD), Dr. Hideaki Hagiwara, learned of the work of Drs. Ivor Royston and Mark Glassy at the UCSD Cancer Center. The researchers were extracting lymph node cells from cancer patients to fuse with a human cell line they had previously developed. The resulting hybrid cell lines generated human hybridomas and produced monoclonal antibodies useful in detecting cancer. Dr. Hagiwara, whose mother in Japan was suffering from
metastatic cancer of the cervix, proposed that the researchers use
his mother's cells to produce a new hybrid cell line that might
have diagnostic potential for cervical cancer. Without legal
formalities, the researchers and Dr. Hagiwara agreed.

After the cell line was developed, the University of
California (UC) filed a patent application. Dr. Hagiwara
objected, however, contending that the propagation of his mother's
genes in the cell line gave his family a right of co-ownership.

He then revealed that his father, the director of a medical
research institute in Japan, planned to produce the antibody there
in order to treat the mother and possibly market the product. The
family made it clear that they were prepared to sue if necessary.

However, negotiations between attorneys for UC and Hagiwara resulted in a settlement in which the family gave up its ownership claim in return for an exclusive license to market the antibody in Japan and Asia and an agreement not to sue.

Another human subject at the University of California took his proprietary claims to court.

2. Moore v. The Regents of the University of California

The crux of John Moore's complaint in Moore v. The Regents of the University of California\textsuperscript{65} is that medical researchers
used his bodily tissues for their research without his consent and
without telling him that they stood to make a great deal of money
from their financial interests in the research. As a result he
sued the university, the researchers, and the business firms who
contracted to exploit the research, on the grounds of various
property interests in his own tissues, as well as lack of informed
consent, breach of fiduciary duty, fraud and deceit, unjust
enrichment, quasi-contract, implied covenant of good faith and
fair dealing, negligent misrepresentation, intentional infliction
of emotional distress, interference with prospective economic
relationships, slander of title, and for accounting and
declaratory relief. The trial court dismissed Moore's first complaint and his amended complaints, but an intermediate appellate court, over one dissent, upheld his cause of action for conversion and reversed with directions to the trial court to rule upon the remaining causes of action. In the process, the court made several novel findings: that a person has a property interest in her own body including her DNA, and that one has power of disposition over one's DNA as well as one's bodily tissues and bodily products.

The facts of the case were that John Moore sought treatment for his hairy-cell leukemia at the University of California, Los
Angeles (UCLA) Medical Center from 1976 through 1983. During his visits, the researchers removed blood and bodily substances, as well as his spleen. The defendants allegedly represented that removal of these substances and organs was necessary for Mr. Moore's treatment, but in addition they used them to establish a cell-line characterized by Mr. Moore's unique combination of DNA, and at first called the Moore Cell-line.\textsuperscript{70}

The researchers early recognized that Mr. Moore's cells had unique qualities and produced valuable products that could be commercially exploited.\textsuperscript{71} Through the university, they applied for patents on the cell-line and the valuable products to be
derived from it. The researchers also contracted with Genetics
Institute, Sandoz Ltd., Sandoz United States, Inc., and Sandoz
Pharmaceutical Corp. to commercially develop the cell-line and
products, predicted to generate over three billion dollars by
1990.\textsuperscript{7a}

Moore alleged he would not have consented removal of his
tissue if he had known of the commercialization that the
researchers planned\textsuperscript{7a}, would have insisted on some measure of
control of the use of his blood and tissue, would have considered
going treatment at another medical facility where his wishes
would have been followed, and would have sought to receive some of
the economic benefits resulting from the commercialization of his blood and tissues.

On appeal the court ruled that Moore had sufficiently pleaded an action for conversion, and that the trial court improperly sustained demurrers to that cause of action. The court first defined conversion as a strict liability tort with three elements: "(1) plaintiffs' ownership or right to possession of the property at the time of the conversion; (2) defendant's conversion by a wrongful act or disposition of plaintiffs' property rights; and (3) damages." Next the court decided that Moore had sufficiently alleged as a matter of law that he has a property
right in his own tissue, extrapolating from law upholding various
rights of dominion over one's body, and concluded that those
"rights and interests are so akin to property interests that it
would be subterfuge to call them something else."

Thus by asserting that the "essence of a property
interest" is the right of control and by demonstrating that there
is a legal right to control of one's body, the court was able to
conclude that an individual has a property right in one's own
body. And a conversion action does not require an unlimited or
unrestricted property right. The court also expressed concern
about the seeming injustice of defendants' claim that only they
had a property right in Moore's tissue and the resulting cell-
line. The court disposed of defendants' argument that the cell-
line belonged to them according to patent law by pointing out that
Moore made no claim to the "ideas gained from study of his cells"
but rather from conversion of the cells themselves and their
progeny. Thus the court ruled that questions concerning the
alteration of those cells were appropriate only to the question of
damages.

However, the court went on to assert that an individual's
property interest in his or her own identity, such as the right of
publicity or privacy, includes a property right in one's genetic
material, the essence of one's material identity:

Plaintiff's cells and genes are a part of his person. Putting aside the effect of environment, "[a]n individual's genotype contains all of the genetic instructions essential for human development, growth, and reproduction....All human traits...are ultimately determined by the information encoded in the DNA." (Gordon Edlin, Genetic Principles -- Human and Social Consequences (1984) pp. 406-407.) If the court's have found a sufficient proprietary interest in one's persona, how could one not have a right in one's own genetic material, something far more profoundly the essence of one's human uniqueness than a name or a face?\(^a\^2\)

The court then concluded that the individual's right to privacy and dignity, at least in the medical context, requires that a patient have "the ultimate power to control what becomes of his or her own tissues."\(^a\^3\) It rejected the Regents' public policy argument that researchers must have free access to human tissue in order to carry out research important to human welfare, and recommended legislative solutions if patients' financial interests
in their tissues led to "unacceptable" financial consequences for
the research enterprise.\textsuperscript{84}

And the court firmly stated that by giving informed consent to
surgery, one does not consent to commercial exploitation of the
excised tissue or even to research on that tissue that is
unrelated to treatment.\textsuperscript{85} Nor does consent to experimental use of
tissues include consent to commercial exploitation of those
tissues.\textsuperscript{86}

Dissenting Associate Justice George took issue with the
majority's conclusion that John Moore had pleaded a sufficient
property right in his own tissue as a matter of law.\textsuperscript{87} He relied
upon the doctrine that state law determines the subject matter of property and criticized the majority's facile analogizing of personal tissue to chattel goods or statutory categories of personal property such as ""money," "things in action," and "evidences of debt."" And he was not persuaded by the majority's simple assertion that the right of dominion over one's body is "so akin to property interests that it would be a subterfuge to call them something else." Such a leap is contraindicated, he argues, by other elements that define property, such as the right transfer and devise property, and even the law of bankruptcy which takes charge of property as part of the
bankrupt's estate.90

Further, even if a property interest were recognized,

Justice George asserts that a patient who has consented to

"surgical removal of his bodily substances" also consents to their

use for scientific purposes under California law.91 This consent,

he asserts, is unqualified as to the scientific uses of the

tissue. It would work a hardship on hospitals and surgeons if

they had to expand consent procedures to include information about

possible research and commercial uses of the removed tissues,

noting "that no perfect dichotomy exists between research and

commercial use."92 And he notes that the consent provisions of
the California Human Subjects in Medical Experimentation Act "do not include any mention of the commercial use which might ensue from experimental research."\textsuperscript{33}

In addition, Justice George argues that even if Moore had a property right in his tissue, the value of that tissue at the time of alleged conversion would be negligible. The tissue became valuable only as a result of the defendants' work on it,\textsuperscript{34} intellectual work, it may be noted, for which they applied and received a patent.

Finally, Justice George is concerned that the majority's recognition of a cause of action for conversion is bad policy. It
would contribute to the "trafficking in human body parts" he worries, and it contradicts existing law prohibiting the sale of human organs. Worse, "If a patient with unusual bodily substances is encouraged (as he or she will be by today's decision) to shop around for the highest bid on the patient's spleen, tissue, blood, or other bodily substance, the quality of health care and medical research undoubtedly will suffer."

Patients could refuse to allow use of their tissues for medical research, and this would be detrimental to public health, it might, for example, slow the fight against AIDS. And he concludes with an appeal to remember that there are some things in life that
money can't buy. He recommends that the legislature develop a regulatory scheme "to balance the vital competing interests of the patient, the health care provider, the commercial research laboratory, and the public at large in the removal and transfer of human bodily substances for research and commercial use."
III. PROPERTY INTERESTS IN HUMAN BODIES, TISSUES, AND BODY PARTS AND PRODUCTS

Now that human tissue, products and bodily parts have potentially high intrinsic value questions about what property rules, if any, to apply will be important. Property rules can serve to prevent or diminish conflict and the use of force or fraud to acquire ownership. The old rule that there is nothing more than a quasi-property interest in dead bodies in order to ensure orderly disposal seems to be inadequate in the light of problems that the Moore case raises.
Certainly the body is essential to personhood and liberty interests, a significant, though often not explicit, characteristic in theories of property rights. The body has many of the attributes of an entitlement because in its various forms, as a whole or as discrete parts, it is an object subject to transfer, custody, and dominion. That alienation of the body and its parts can be restricted by law may simply mean that liability rules rather than property rules are being applied to the entitlement. Liability rules, of course, require that owners of entitlements be compensated for losses, while property rules generally permit the owner to transfer the property by sale or
gift, or simply to dispose of it as waste.\textsuperscript{103} Some modified inalienability may be imposed on property, for example, when a person may dispose of property only as a gift. The National Organ Transplantation Act, for example, prohibits sale of body organs, but does permit their donation.

A. Market Approaches to the Body as Property

Bodily tissues and properties have some of the characteristics of property. They may be donated, for example, for research use or for therapeutic use. Some bodily products, such as blood and semen, may be sold, although generally bodily
products are subject to modified inalienability rules which forbid sales but permit or encourage gifts for various policy reasons.\footnote{104}

According to market theory, inalienability is imposed for various public policy reasons including paternalistic imposition of moral values and redistribution of wealth, or because of market failure.\footnote{105} Market failure may arise from externalities, imperfect information, or problems in coordination.\footnote{106} The advantage of permitting alienability, of course, is the presumable increase of supply that will follow.\footnote{107} Where dangers of substandard quality are not a problem, alienability appears to be an efficient rule.

One argument for prohibiting sale of blood, however, is to
discourage sellers from producing bad quality, even dangerous, blood and blood products, contaminated by hepatitis or AIDS for example. There may be solutions to quality control, however, other than alienability, such as liability for damages and careful screening of donors, etc.

In some cases supply may be complicated by monopoly problems, however, as in the cases where a person has a rare blood type and is able to sell blood to pharmaceutical companies at very high prices, possibly raising the price of drugs beyond the ability of sick people to pay. The high price paid to the blood producer might not be significant, however, if the market for the
pharmaceutical product is very large, other costs of production are relatively low, and the profit is high. Further, in such a situation, the blood producer may be reluctant to make a charitable donation to the pharmaceutical firm, and thus restrict ultimate benefits to sick persons.\textsuperscript{103} Thus dual systems of modified alienability that prohibit the original producer from selling the product but allow his or her donee to do so may be inefficient, i.e., result in undersupply.\textsuperscript{110}

While the argument for modified inalienability of blood and blood products is persuasive because it purports to ensure a high quality supply, that argument is not necessarily appropriate for
supply of other human tissue. Indeed, "contaminated," as well as
highly unique tissue may be most desirable for research purposes.

The problem of monopoly control may then arise, that is, the
possessor of special tissue may wish sell it, quite naturally, to
the highest bidder, thus making it too expensive for some
interested researchers to obtain the material for their research
purposes.¹¹² Such a problem could be resolved, however, by
permitting alienability, but regulating prices.¹¹² Economists, on
the other hand, generally assume that higher value uses result
from voluntary transactions.¹¹³
Restrictions on the ownership of one's own body and bodily tissues and products which permit others to profit from these materials seem both paternalistic and opportunistic. That is, researchers and universities that received donated tissue, for example, then have monopoly power and the exclusive right to potential profits. Such a result seems to violate ideals that we cherish, as a people, of individual liberty and social utility, and perhaps distributive justice.
B. Personhood Approaches to the Body as Property

Property rights are essential to personhood in most Western theories of political science from communitarianism to conservatism. Property is essential to survival and autonomy interests, as well as to community life. Professor Margaret Radin has defined a theory of property based on one's identification with objects, that is, "personal embodiment of self-constitution in terms of 'things.'" Although crucial criterion for her theory is the strength of the pain one feels at the loss of the property, her theory is based on more than subjective preferences. Rather, she attempts to explain the
relationship to property in terms of the concept of the person.

Hence this property will frequently be inalienable because it is so closely tied to the concept of the person, which is inalienable. Thus laws prohibit selling oneself into slavery or committing suicide.

Slightly further down the continuum, however, is the sale of human body parts. Once removed from the body, especially if they are replaceable body parts and no longer of personal use, human bodily materials may lose some of the characteristics of property closely identified with personhood. The closer the property is to the person subjectively, and hence the more
indispensable it is, then the more likely it is personal property for personhood. But if it is not indispensable, and if it is interchangeable with money, then it is probably not property for personhood.¹¹⁸ Property for personhood thus is defined by what Professor Radin calls "indicia of personhood,"¹²⁰ which are recognized by the person subjectively as central to his or her identity.

Presumably, a person has little or no interest or identification in bodily materials that have been removed from the body and which have been generally labeled as waste materials.

Because waste materials are products of the human body, however,
respect for human beings often requires that the waste be disposed of in an orderly and respectful fashion, as well as for reasons of health and hygiene. Hence laws regulate disposal of dead bodies and bodily materials.

These laws and principles do not necessarily require recognition of a full property interest in human tissue. For example, similar concerns for respect for human dignity, autonomy, and privacy prompt tort protection against assault and battery, and common law rights of privacy. The common law privacy interests have something in common with the concept of property for personhood, as for example the appropriation of a person's
name or likeness without consent and for a commercial purpose, or

the exposure of very private personal facts about a person.\textsuperscript{121}

The court in Moore recognized this parallel but indicated that

one's genetic material is even more worthy of respect and legal

recognition as a proprietary interest, recognizing it as property

that is akin to personhood in basic form.\textsuperscript{122} Thus the Moore court

confidently found a cause of action for conversion of Moore's

tissues by the UCLA researchers who developed a cell line worth

potentially billions of dollars.\textsuperscript{123}

The Moore court's ruling seems reasonable because bodily

tissue, including blood, is separable from the body and either
replaceable or removed as a consequence of medical necessity. And there is long-standing precedent for sale of similar bodily products — blood and semen, for example. The costs of heightened concern for human subjects should not be high, generally, however.

Most human products needed for research are not valued for their unique genetic composition. When unique human genes are required, on the other hand, it seems just to permit a person to be compensated for their use. Whether such material should be protected additionally because one's genetic make-up is closely related to personhood is not as clear. Few people conceive of their bodily tissues as genetic representations of themselves as
persons. It may be enlightening to consider how fingerprints are used and protected however. Generally, one must consent to fingerprinting, and records are maintained with some attempts at security. Thus analogously, it would seem that one's consent should be obtained for removal of tissue that also identifies one as a unique individual, particularly when that identity will be perpetuated indefinitely in cell lines. Respect for persons as ends, not means, seems to demand as much.
CONCLUSION

I have tried to show that commercialization of university-based research has reconstituted the relationship of researchers and human subjects. Slowly research institutions and positive law are responding to the new commercial character of research.

Normative guidelines are necessary, as well. Thus I have analyzed the relationship in terms of the researcher as economic man, a trader, and the human subject as the source of valuable raw materials. In this light, the relationship must either be reconceived as at arms-length or as one of heightened fiduciary duty, including broader disclosure requirements, in which the
researcher acts as a quasi-trustee of the financial interests of the human subject.

1. Experimental drug trials are an exception to this policy.

2. See infra notes and accompanying text.

Congress conducted hearings regarding this problem in 1981 and 1982, Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, 97th Cong. 1st Sess. (1981); University/Industry Cooperation in Biotechnology: Hearings Before the Subcomm. on Investigation and Oversight and the Subcomm. on Science, Research and Technology of the Comm. on Science and Technology, 97th Cong., 2d Sess (1982), some of which focused on the case of John Moore discussed infra notes and accompanying text.


5. There are many definitions of basic and applied research. The distinction that I mean depends on the goal of the research, basic research implying no commercial or applied consequences as a significant goal.


8. After World War II, federal support of research expanded to a peak of
73.5% of all funding in 1966, and then began to decline, to 65.1% in 1981. At the same time, however, industry almost doubled its support of basic research at universities, from 2.4% to 3.8%. Fowler, University-Industry Research Relationships: The Research Agreement, 9 J.C. & U.L. 515 (1982-83).


13. See Sections 501(c)(3) and 44F.


15. See Bouton, supra note .


Professor Eisenberg discusses the motivation for secrecy in the conduct of research that stems both from the norms of science which reward primacy of discovery and from commercialization which values monopolization on profit-making knowledge, processes, and products. Eisenberg, supra note 3.

18. See, e.g., the failure of SmithKline pharmaceutical company to find new drugs in recent years despite investing heavily in research and development, although SmithKline's problems have been attributed to poor management. Companies Search for Next $1 Billion Drug, NY Times, Nov. 28, 1988, at D1, col. 3.

19. Harvard University, for example, waited years before adopting a plan in 1988 to raise money from private investors to market the discoveries of its medical researchers, and return 10% of the profits to the University, through a series of limited partnerships with industry. See, e.g., Harvard to Seek
Research Profits, University Will Raise Money to Invest in Faculty Work — Policy is Reversed, NY Times, Sept. 15, 1988, at A21, col. 1; Academic Research for Financial Gain, NY Times, Sept. 16, 1988, at A14, col. 1. Derek Bok, President of Harvard University, explained why the University declined to engage in commercialization of the work of the universities researchers when the issue first came up in the 1970s. D. Bok, The President's Report (1979). Other universities have chosen to accept university links, but have declined the involvement of equity partnerships. Yale University, for example, limits its efforts to securing and coordinating corporate sponsorship of research, and has established an administrative Cooperative Research Office for the purpose of building links between the University's science departments and private business. See Yale Won't Follow Harvard Policy, Crimson Reverses Itself, Promotes Business Involvement in Research, New Haven Register, Sept. 15, 1988, at 59, col. 2; Business Rents a Lab Coat and Academia Hopes for the Best, NY Times, Feb. 21, 1982, at 7, col. 1. Commercial investments in Yale research have grown from $800,000 in 1982 to over $9 million in 1988. See Yale's Share in Research Is Patently Significant, New Haven Register, Dec. 8, 1988, at 3, col. 6.

20. Patenting also produces a considerable source of income from royalties and licensing fees. Last year earnings from this source amounted to approximately $500,000 for Yale, $9.1 million for Stanford, $3 million for
MIT, and $1 million for Harvard. The average formula for distributing this income is to award 30% to the researcher, and sometimes his or her department, 40% to the university (my source doesn't say what happens to the remaining 30%!). See Yale's Share in Research Is Patently Significant, New Haven Register, Sept. 8, 1988, at 3, col. 6, interviewing Robert K. Bickerton, director of Yale's Office of Cooperative Research. Universities and researchers may secure additional income by investment in and or employment with private entities that purchase the licenses to develop and market commercial products.


23. For an analysis of the conjunction of the norms of commerce and science, see Eisenberg, Proprietary Rights, supra note .

24. Researchers in other scientific fields, such as engineering and
chemistry, however, have been dealing with commercialization of research for decades. See 1981 hearings, supra note


26. For a review of some of these affiliations, see Culliton, Biomedical Research Enters the Marketplace, 304 New Engl. J. Med. 1195 (1981).

27. See discussion infra notes .

28. Other areas of scientific research have been dealing with similar issues of commercialization for many years, especially in engineering and chemistry. See hearings on commercialization, supra note .

29. This is a matter of common knowledge in the science community, and will be confirmed by an interview with the university's sponsored projects office about it.

30. See Bouton, supra note


32. Most of these disclosure requirements originally targeted faculty consulting and generally limited consulting activities to one or two days per


34. For a definition, see Ackerman, \textit{Talking and Trading}, 85 Colum. L. Rev. 899 (1985).

35. See, e.g., California's statute declaring rights of human subjects, infra note 28.


37. 45 C.F.R. § 46.107(b)

38. I know this from my own experience on an IRB at Albany Medical College last year.


40. The federal guidelines specifically address procedures for obtaining informed consent. See 45 CFR and 21 CFR.

41. 45 CFR 46.116(a)(1)-(8).
42. A number of physicians and research scientists have recommended that the consent forms should include a provision that the human subject is willing to forego any rights to the commercialization of the research. See, e.g., Levine, *Research that Could Yield Marketable Products from Human Materials: The Problem of Informed Consent*, 8 IRB 6 (Jan./Feb. 1986). Leon Rosenberg, Dean, Yale University School of Medicine, also believes that research protocols should explicitly explain the human subjects will not share in any commercial gain from the research. Rosenberg, *Using Patient Materials for Product Development: A Dean's Perspective*, 33 Clin. Res. 452 (Oct. 1985). See discussion infra notes .

43. 45 CFR 46.109(e).


45. Nicholas Christakis identifies some of these populations as the "incarcerated, the mentally infirm, the young," etc. Christakis, *Should IRBs Monitor Research More Strictly?* 10 IRB 8, 9 (Mar./April 1988).


49. For a discussion of conflict of value, see Shultz, From Informed Consent to Patient Choice: A New Protected Interest, 95 Yale L.J. 219, 272-73 (1985) (opposition of interests is not as "crystallized" as in conflict of interest situations).

50. For a discussion of the conflict of value between subject and researcher, see Bridging the Gap, supra note .

51. For a review of the motivations of researchers, see B. Barber, J. Lally,


53. See, e.g., articles by Levine and Rosenberg, supra note .


56. See Holder, Do Researchers and Subjects Have a Fiduciary Relationship?, 4 IRB 6 (Jan. 1982) (raising the possibility that researchers and subjects have a fiduciary relationship). See also Bridging the Gap, supra note , at 107.


58. For a discussion of this view of personhood, see Radin, Property and Personhood, 34 Stanford L. Rev. 957, 963 (1982). Professor Radin cites theorists who suggest "that the individual's ability to project a continuing
life plan into the future is as important as memory or continuing consciousness." Id. at 963, citing Williams, Persons, Character and Morality, in The Identities of Persons 197 (A. Rorty ed. 1976).


60. See Blumberg, supra note .

61. See Bridging the Gap, supra note , at 126.

62. For a review and analysis of procedures for obtaining informed consent, see Bridging the Gap, supra note ; Silva & Sorrell, Enhancing Comprehension of Information for Informed Consent: A Review of Empirical Research, 10 IRB 1 (Jan./Feb. 1988).

63. See also Bridging the Gap, supra note .

64. Medical schools confirm that pharmaceutical companies sponsor research that pays subjects for their participation. The FDA routinely pays volunteers for drug trials.

65. For the facts of the Hagiwara dispute, see Rosenberg, Using Patient


67. Based on both state and federal law. See Third Amended Complaint; 45 C.F.R. § 46; Protection of Human Subjects in Medical Experimentation Act of California, Cal. Health & Safety Code § 24172 (West 1977) (including "Experimental Subject's Bill of Rights").

68. Third Amended Complaint, at 499.

69. Id. at 503.

70. Defendants changed the name of the cell line to RLC at some point, allegedly to prevent plaintiff from learning of it. Moore, at 501.

71. By using recombinant DNA techniques researchers can take genetic material from a cell (by directly excising genes from the cell or by synthesizing the DNA sequence or by using reverse transcriptase to produce copies of the DNA) and insert it into microorganisms which will then produce the same proteins as the original cell but on a large scale.

72. Id. at 501.
73. On one occasion, Moore signed a consent form, April 11, 1983, and on Sept. 20, 1983 again signed a consent form, but indicated he did not consent to giving defendants any rights to his cell-line. Moore, at 501.


The court also cited statutes re the right of individuals to make medical decisions about their bodies and statutes regulating donation of human organs and tissues. Calif. Health & Safety Code, § 7100 (disposition of human
remains); Calif. Health & Safety Code, § 24171 (right to determine what is done to one's own body); the Uniform Anatomical Gift Act.

76. Id. at 505.

77. Id. at 507.

78. Id.

79. Id. at 507 ("Apparently, defendants see nothing abnormal in their exclusive control of plaintiff's excised spleen, nor in their patenting of a living organism derived therefrom."

80. Id.

81. Id., referring to discussion of damages in Note, Toward the Right of Commerciality, 34 UCLA L. Rev. 207 (1986).

82. Id. at 508.

83. Id.

84. Id. at 509.

85. Id. at 510.

86. Id. 15 511.

87. Id. at 533.

89. Id. at 534, citing majority opinion at 505.

90. Id. at 535.

91. Id. at 535-36, citing Calif. Health & Safety Code § 7054.4 (bodily substances "following conclusion of scientific use...be disposed of by interment, incineration, or any other method determined by the state department to protect the public health and safety").

92. Id. at 536.

93. Id.

94. Id. at 538.

95. Id. at 538, citing Calif. Pen. Code, § 367f; The Uniform Anatomical Gift Act; the National Organ Transplant Act; Calif. Rev. & Tax Code, § 33 (exempting human blood and blood products from taxation).

96. Id. at 540.


98. For a review of the law of property regarding human bodies, see Katz,

101. Radin, Property and Personhood, supra note .


103. See id.; see also Rose-Ackerman, Inalienability and the Theory of Property Rights, 85 Colum. L. Rev. 931 (1985).


105. For a discussion of these topics, see Rose-Ackerman supra note .

106. Id. at 938.

77107. For a discussion of the efficiency of making human tissue alienable, see Note, Toward the Right of Commerciality: Recognizing Property Rights in


107. For a review of possible alternatives and relevant sources, see Rose-Ackerman, supra note , at 946.

108. See, e.g., United States v. Garber, 607 F.2d 92 (5th Cir. 1979).

109. Consider the widely-cited example of the young man with rare blood who donated his blood to university researchers for research purposes, but sold it for commercial use to a pharmaceutical firm. See, e.g., Murray, Who Owns the Body? On the Ethics of Using Tissue for Commercial Purposes, 8 IRB 1 (Jan./Feb. 1986).

110. Professor Rose-Ackermann makes this point with regard to blood, supra note , at 947.

112. See, e.g., Rose-Ackerman, supra note , at 949 (regulate prices "so that they reflect the marginal costs and risks borne by the donor).

113. Epstein, supra note , at 972.

114. See, e.g., the work of welfare rights theorists such as Reich's *The New Property*.


116. Radin, supra note , at 958.

117. Id. at 986 n.101.

118. Id.

119. Id. at 966.

120. Id. at 979

121. For a discussion of the history of this tort, see W. L. Prosser, *The Law of Torts* (4th ed. 1971). One commentator has developed a common law property right in human tissue by extrapolating from this body of law. See Note, *Toward the Right of Commerciality*, supra note .

122. Moore, supra note at, 508. See also Note, *Toward a Right of Commerciality*, supra note .
123. See estimates quoted in Moore, supra note . The court did not recognize any new causes of action, however, such as the right to commerciality proposed in Toward a Right of Commerciality, supra note .